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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,374	02/16/2001	Anthony M. Looper	VM 6010.2	5023

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EXAMINER

PATEL, MITAL B

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/785,374	Applicant(s) LOOPER ET AL.	
	Examiner Mital B. Patel	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-89 is/are pending in the application.
- 4a) Of the above claim(s) 22-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-21 in Paper No. 7 is acknowledged. Please note that claims 2 and 14 have been previously canceled. Therefore, only claims 1, 3-13, and 15-21 are pending.

Claim Objections

2. Claims 1 and 3-12 are objected to because of the following informalities: In Claim 1, Applicant uses the term "adopted". For sake of clarity, the Examiner suggests the term --adapted--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1, 3-12, 13, and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. As set forth by claims 1 and 13, it is unclear as to what exactly the Applicant means by the term "fatigue resistant". Applicant has not provided sufficient language and structure in the claims to define "fatigue resistant".

Art Unit: 3761

6. In Claim 1, the Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the malleable shaft member alone or the combination of the shaft member and surgical device and the actuating means. The Applicant sets forth the combination of the shaft member and the actuating means when describing the actuating means **extending axially through the first tube**, which is inconsistent with the preamble, that sets forth the subcombination of the shaft member. Applicant is required to make the language of the claims consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the Examiner will consider the claims as drawn to the subcombination. Furthermore, the Examiner suggests amending the claim to read --the actuating means adapted to extend axially through the first tube--.

7. In Claim 8, the Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the malleable shaft member alone or the combination of the shaft member and the handle assembly. The Applicant sets forth the combination of the shaft member and the handle assembly when describing the first tube is removably **coupled to the handle assembly**, which is inconsistent with the preamble, that sets forth the subcombination of the shaft member. Applicant is required to make the language of the claims consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the Examiner will consider the claims as drawn to the subcombination. Furthermore, the Examiner suggests amending the claim to read -
-the first tube adapted to be removably coupled to the handle assembly--.

Art Unit: 3761

8. In Claim 9, the Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the malleable shaft member alone or the combination of the shaft member and the tissue engaging means. The Applicant sets forth the combination of the shaft member and the tissue engaging means when describing the first tube is removably **coupled to the tissue engaging means**, which is inconsistent with the preamble, that sets forth the subcombination of the shaft member. Applicant is required to make the language of the claims consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the Examiner will consider the claims as drawn to the subcombination. Furthermore, the Examiner suggests amending the claim to read --the first tube adapted to be removably coupled to the tissue engaging means--.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al (US 5916193).

11. **As to claim 1**, Stevens teaches a malleable shaft member for a surgical device having a tissue engaging means and a handle assembly, and an actuating means connecting the handle assembly and the tissue engaging means for actuating the tissue

Art Unit: 3761

engaging means, the shaft member **320** comprising a first tube **322** made of a malleable material and having a proximal end **326**, a distal end **324** and a longitudinal axis, the proximal end of the first tube adapted to be coupled to the handle assembly, the distal end of the first tube adapted to be coupled to the tissue engaging means, the actuating means adapted to extend axially through the first tube, the first tube configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube (See Col. 27, lines 45-67 and Col. 28, lines 1-21). Stevens is silent to the specific range of bending moment. However, Applicant has not provided sufficient structure to result in structural differences between the claimed invention and the shaft of Stevens and therefore, the shaft member of Stevens is fully capable of bending in the range disclosed.

12. **As to claims 3-4**, the Applicant has not provided sufficient language and structure to result in structural differences between the claimed invention and the shaft of Stevens, and therefore, the shaft member of Stevens is fully capable of bending in the range disclosed.

13. **As to claims 5 and 7**, Stevens teaches essentially all of the limitations except for the specifics of the wall thickness. However, it would be obvious to one of ordinary skill in the art to arrive at the particular dimensions depending on what specific medical procedure or surgical procedure the shaft member was required from since different sized tubes are used for different parts of the body when performing a surgical or medical procedure.

14. **As to claim 6**, Stevens teaches a shaft member wherein the first tube is made of material selected from the group consisting of stainless steel, copper, aluminum, and brass.

15. **As to claim 8**, Stevens teaches a shaft member wherein the proximal end of the first tube is adapted to be removably coupled to the handle assembly.

16. **As to claim 9**, Stevens teaches a shaft member wherein the distal end of the first tube is adapted to be removably coupled to the tissue engaging means.

17. **As to claim 10**, Stevens teaches a shaft member further comprising a second tube **352**, the first tube coaxially aligned and disposed within the second tube (See Col. 26, lines 27-29).

18. **As to claim 11**, Stevens teaches a shaft member wherein the second tube is made of material selected from the group consisting of aluminum, brass, copper and plastic.

19. **As to claim 12**, Stevens teaches a shaft member wherein the first and second tubes are formed from co-extrusion (See Fig. 29B).

20. Claims 13 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donahue (US 5643303).

21. **As to claim 13, As to claim 1**, Donahue teaches a surgical device (Fig. 8) comprising a tissue engaging means **50,54**; a handle assembly **52**, and an actuating means **46** connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means, a malleable shaft member **42** comprising a first tube made of a malleable material and having a proximal end, a distal end and a longitudinal axis,

the proximal end of the first tube coupled to the handle assembly, the distal end of the first tube coupled to the tissue engaging means, the actuating means extending axially through the first tube, the first tube configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube (See Col. 5, lines 4-26). Donahue is silent to the specific range of bending moment. However, Applicant has not provided sufficient structure to result in structural differences between the claimed invention and the shaft of Donahue and therefore, the shaft member of Donahue is fully capable of bending in the range disclosed.

22. **As to claim 15**, the Applicant has not provided sufficient language and structure to result in structural differences between the claimed invention and the shaft of Donahue, and therefore, the shaft member of Donahue is fully capable of bending in the range disclosed.

23. **As to claim 16**, Donahue teaches essentially all of the limitations except for the specifics of the wall thickness. However, it would be obvious to one of ordinary skill in the art to arrive at the particular dimensions depending on what specific medical procedure or surgical procedure the shaft member was required from since different sized tubes are used for different parts of the body when performing a surgical or medical procedure.

24. **As to claim 17**, Donahue teaches a shaft member wherein the first tube is made of material selected from the group consisting of stainless steel, copper, aluminum, and brass.

Art Unit: 3761

25. **As to claims 18 and 19**, Donahue teaches essentially all of the limitations except for wherein the shaft member is removably coupled to the handle assembly and the tissue engaging means. However, it would have been obvious to one of ordinary skill in the art to make the parts removably couplable so that if a part needed to be replaced it would be easier to replace the part than the entire device. Furthermore, it would be obvious to one of ordinary skill in the art to make the parts removably couplable so that the parts can be easily cleaned.

26. **As to claim 20**, Donahue teaches a surgical device further comprising an outer tube **44**, the first tube coaxially aligned and disposed within the second tube.

27. **As to claim 21**, Donahue teaches a surgical device wherein the outer tube is made of material selected from the group consisting of aluminum, brass, copper and plastic.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6212426, US 5855590, US 5833692, US 5782834, US 5499997, US 5325866, and US 3964468.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on 703-308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
June 27, 2002


DENNIS RUHL
PRIMARY EXAMINER